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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,056

02/07/2007

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0516US-Expandis

6365

23521 7590 12/16/2009  
SALTAMAR INNOVATIONS  
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EXAMINER

SCHNEIDER, LYNN SY M

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

12/16/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,056	<b>Applicant(s)</b> SHEZIFI ET AL.	
	<b>Examiner</b> LYNNSY SCHNEIDER	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 September 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-9,11,12 and 14-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-9,11,12 and 14-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/11/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the expansion members of claims 9 and 14-22 in use with an introduction member having a distal end with two opposing slots, and the second introduction member of claim 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 9, 14-22, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claims 9, 14-22, the disclosure as originally filed does not provide support for the introduction member having a distal end with two opposing slots and the expansion member as disclosed in dependent claims 9 and 14-22. The various embodiments claimed in claims 9 and 14-22 either disclose a conduit 18 that does not have two opposing slots, or do not disclose a conduit at all. Claim 1 as originally filed was generic, but the amendment to claim 1 made it specific to a select number of embodiments. Claims 9 and 14-22 are drawn to embodiments that are not encompassed by claim 1.

b. Regarding claim 17 and 30, the disclosure as originally filed does not provide support for a second introduction device, wherein the wrapping is incorporated with the second introduction device.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 3733

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1, 4, 6-9, 11, 12, 14-31 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites the limitation "the patient's body". There is insufficient antecedent basis for this limitation in the claim.

7. Claim 6 is dependent upon a cancelled claim. For examination purposes, claim 6 will be interpreted to depend upon claim 1.

8. Claims 6 and 7 recite the limitation "the two substantially opposing support surfaces". There is insufficient antecedent basis for this limitation in the claims.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1, 6-8, 9, 14, 29, 30, and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnson et al. (Pub. No. US 2002/0183761 A1).

Regarding claims 1, 9, 14, 29, 30, and 31, Johnson et al. discloses a device (figure 29) for distracting and supporting two substantially opposing tissue surfaces in a patient's body, the device comprising: a wrapping element (paragraph 0177 "permeable

Art Unit: 3733

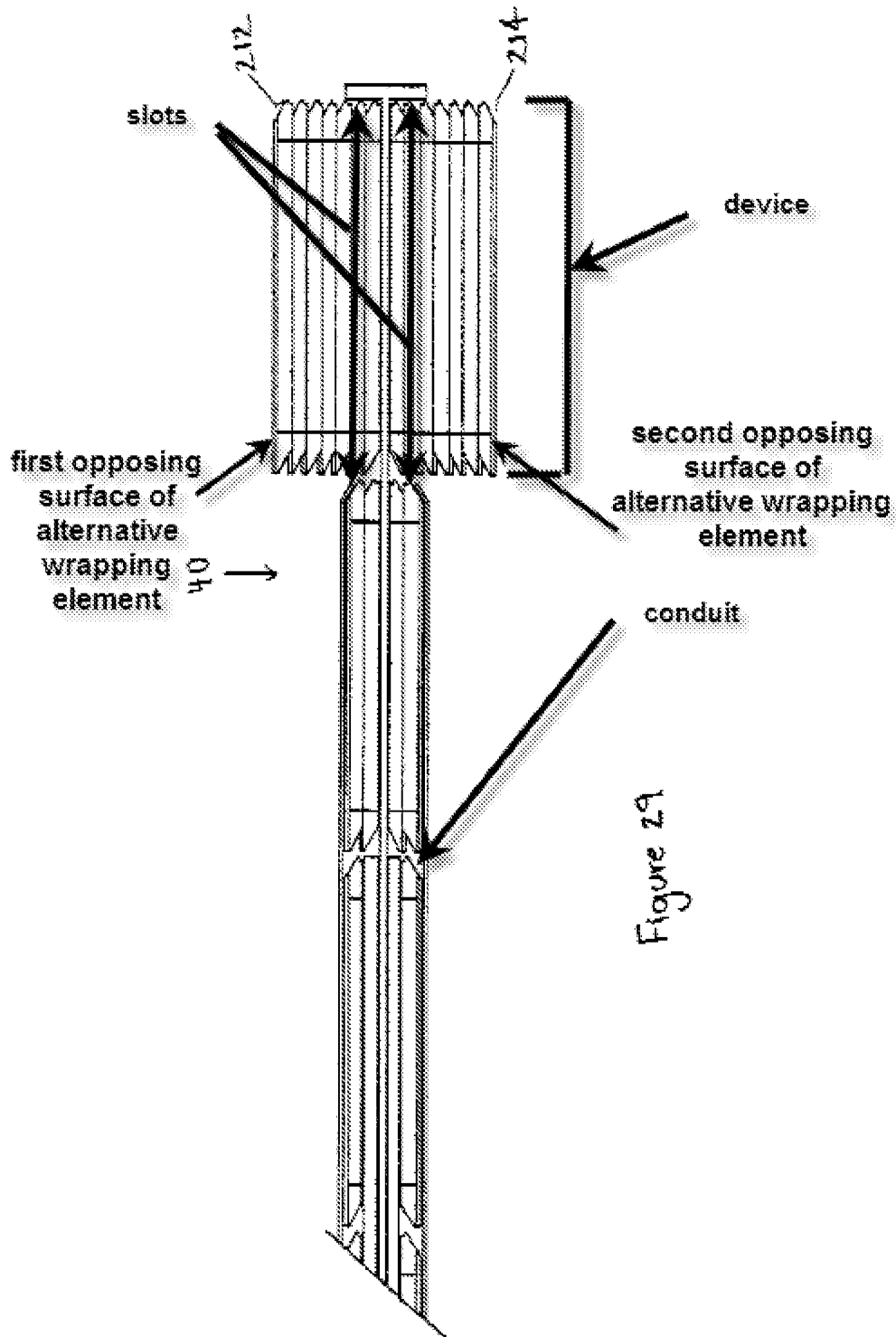
membrane”); an expandable structure “wafers” insertable between two opposing support surfaces of the wrapping element, and adapted to be expanded between the two substantially opposing tissue surfaces to a predetermined dimension (figure 29); and an introduction member 40 (figure 29), the introduction member 40 comprising a substantially linear conduit (figure 29), having a proximal end through which the expandable structure is inserted and a distal end having two substantially opposite slots (figure 29) through which the expandable structure deploys in directions substantially perpendicular to the conduit (figure 29), wherein the implant device is adapted to remain implanted in its entirety in the patient’s body (Paragraphs 0031, 0035 disclose that the wafers and insertion device are each adapted to remain in the body. Although Johnson does not explicitly disclose the device in its entirety remaining implanted in the body, the device is adapted to remain implanted in its entirety since each of the wafers, wrapping element, and introduction member are adapted to remain implanted). The expandable structure comprises a segmented strip (figures 32 and 33) made of a series of jointed segments 220 pivotally interconnected (via tethers 218) so as to present a multi-joint strip, each segment having an elongated bore “holes” provided on it through which a fastener “bone filler” may be interlaced, for holding the strip in a folded state of a desired height (paragraph 0128). The expandable structure comprises two foldable straps placed on either sides of a bar (figure 29 discloses two separate wafer stacks, and paragraph 0132 discloses that the wafers can be tethered. The tethered wafers form a foldable strap. Therefore, each wafer column comprises a foldable strap.) The wrapping is incorporated with the expandable structure (paragraph 0177). The

Art Unit: 3733

wrapping is incorporated with an introduction device 40 used to introduce the device to a target location (since the wrapping surrounds the wafers, and the wafers are incorporated with the introduction device, the wrapping is also incorporated with the introduction device). The device is constructed of materials selected from a group consisting of: metal, titanium, titanium alloy, stainless steel alloys, steel 316, processed foil, hydroxyapatite, material coated with hydroxyapatite, plastics, silicon, composite materials, carbon-fiber, hardened polymeric materials, polymethylmethacrylate, ceramic materials, coral material, or a combination thereof (paragraph 0097).

Regarding claims 6-8, the wrapping element is alternatively formed by the top wafer of each stack (paragraph 0130), the top wafer having a ridged internal surface (figures 24-26). The top wafers form two opposing support surfaces that are provided with a protrusion 142 (figure 24) for providing anchorage for the expandable structure (the wafers in between the top wafers) when it is positioned between the two substantially opposing support surfaces. The expandable structure comprises a plurality of beams "wafers" (figure 29).

Art Unit: 3733





Art Unit: 3733

11. Claims 1, 4, and 29-30 are rejected under 35 U.S.C. 102(a) as being anticipated by Weikel et al. (Pub. No. US 2002/0177866 A1).

Regarding claims 1, 4, and 29-30, Weikel et al. discloses an implant device (figure 14) for distracting and supporting two substantially opposing tissue surfaces in the patient's body, the device comprising: a wrapping element 162 (figure 14); an expandable structure "filler" (paragraph 0057) insertable between two opposing surfaces of the wrapping element, and adapted to be expanded between the two opposing tissue surfaces to a predetermined dimension; and an introduction member 165 (figure 14) comprising a substantially linear conduit having a proximal end through which the expandable structure is inserted and a distal end having two substantially opposite slots 170 through which the expandable structure "filler" deploys in directions substantially perpendicular to the conduit (figure 14); wherein the implant device is adapted to remain implanted in its entirety in the patient's body (the implant device is sized and shaped to remain implanted in its entirety). The wrapping element 162 comprises an adjustable strap 162 interlaced through slits 170 that are provided on the introduction member 165 (figure 14). The wrapping element is incorporated with the expandable structure (since the filler expands the wrapping element 162). The wrapping 162 is incorporated with the introduction device 165 (figure 14).

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3733

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1, 9, 11, 12, 14, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bhatnagar et al. (Pub. No. US 2005/0080425 A1, which incorporates by reference applications 10/389,818 filed on March 18, 2003 and 60/365,026, filed on March 18, 2002) in view of Weikel et al. (Pub. No. US 2002/0177866 A1)..

Regarding claims 1, 9, 11, 12, 14, 29, and 30, Bhatnagar et al. discloses a device for distracting and supporting two substantially opposing tissue surfaces in a patient's body (figure 9), the device comprising: a wrapping element 84 (figure 9); and an expandable structure 16 (figure 9) insertable between two opposing support surfaces of the wrapping element 84 (figure 9), and adapted to be expanded between the two substantially opposing tissue surfaces to a predetermined dimension (figure 9; paragraph 0059); and an introduction member 44 (figure 8A) comprising a substantially linear conduit having a proximal end through which the expandable structure 16 is inserted (paragraph 0049). The expandable structure 16 deploys in directions substantially perpendicular to the conduit 44 (figures 8A and 8B). The wrapping element 84 comprises two substantially opposing support surfaces (figure 9). The expandable structure 16 comprises a plurality of beams 56, 58, 64 (figure 9). The expandable structure 16 comprises a segmented strip made of a series of jointed segments 56, 58, and 64 pivotally interconnected (figure 9) so as to present a multi-jointed strip (figure 9) each segment 56 and 58 having an elongated bore (illustrated in figure 9) provided on it through which a fastener may be interlaced, for holding the strip

Art Unit: 3733

in a folded state of a desired height (fasteners connect actuation rod 46 to segments 56 and 58. The actuation rod holds the strip in a folded state of a desired height, figure 9). The expandable structure 16 is an initially squashed deployable polyhedron structure (figures 8A and 8B). The polyhedron structure has a cross section in the form of a parallelogram (figure 9). The expandable structure comprises two foldable straps 56/58/64 placed on either sides of a bar 46 (figure 9). The wrapping 84 is incorporated with the expandable structure 16 (paragraph 0059). The wrapping 84 is incorporated with an introduction device 44 used to introduce the device 16 to a target location (paragraph 0059). The expandable structure 16 is an initially collapsed deployable polyhedron structure (figures 8A and 8B). The polyhedron structure has a cross section in the form of a parallelogram (figure 8A). The device is adapted to remain implanted in its entirety in the patient's body (since the device comprising sections 14 and 16 is releasable from the handle section 12 (paragraph 0044), and is sized and shaped to fit in the body, it is adapted to remain implanted in its entirety in the patient's body)

Bhatnagar et al. does not disclose that the introduction member 44 has two substantially opposite slots through which the expandable structure deploys. However, Bhatnagar et al. does suggest that alternative embodiments of assembly 14 (which includes introduction device 44) can be used.

Weikel et al. teaches an introduction device 165 (figure 14) having a linear conduit through which an expandable structure "filler" is inserted, the introduction device having two substantially opposite slots 170 (figure 14) through which the expandable structure 145 deploys.

It would have been obvious to one skilled in the art at the time the invention was made to substitute the introduction device disclosed by Bhatnagar et al. with the introduction device taught by Weikel et al. to achieve the predictable result of providing a conduit to guide the expandable structure.

14. Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikel et al. in view of Baumgartner (Pat. No. US 5,755,797).

Regarding claims 23-28, Weikel et al. discloses the claimed invention except for the expandable structure comprising a plurality of cylindrical elements, wherein the cylindrical elements are linked loosely by links that can break up when the linked cylindrical elements are pressed within the wrapping element, wherein the cylindrical elements are linked by a string.

Baumgartner discloses a device for distracting and supporting two substantially opposing tissue surfaces in a patient's body (figure 3), to be introduced within the tissue surfaces in a minimally invasive procedure (figure 3), the device comprising: a wrapping element 10 (figure 3); and an expandable structure 7 (figure 3) insertable between the two substantially opposing support surfaces of the wrapping element 10 (figure 3), adapted to be expanded between the two substantially opposing surfaces to a predetermined dimension (figure 9). The expandable structure comprises a plurality of cylindrical elements 7 (col. 4, lines 66-67) that are linked loosely by a string 20 (figure 7) that can break up when the linked cylindrical elements 7 are pressed within the wrapping element 10 (functional language- the links 20 are capable of breaking upon

Art Unit: 3733

the application of pressure due to their reduced diameter as shown in figure 7). The device is made of a plastic material (col. 1, line 66-col. 2, line 4 and col. 2, lines 60-67).

It would have been obvious to one skilled in the art at the time the invention was made to substitute the expandable structure disclosed by Weikel et al. with the linked cylindrical elements taught by Baumgartner to achieve the predictable result of expanding the wrapping element and providing support to the implant structure.

Regarding claims 24 and 25, Weikel et al. as modified by Baumgartner does not disclose that the cylindrical elements are provided with cog-like surfaces or with threading. However, It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to provide the cylindrical elements with cog-like surfaces or threading, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of expanding a wrapping element. In re Dailey and Eilers, 149 USPQ 47 (1966).

15. Claims 15, 16, and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weikel et al. in view of Baumgartner (Pat. No. US 5,171,280).

Regarding claims 15, 16, and 18-22, Weikel et al. discloses the claimed invention except for the expandable structure comprising a coiled strap, the coiled strap being coiled over a rotor, the coiled strap including a propulsion belt for driving the strap and enhancing its coiling, the device further comprising a roller for rolling the propulsion belt, wherein the belt is provided with a ragged surface for enhancing friction between the

Art Unit: 3733

belt and the coil, or wherein the strap is provided with a ragged surface for enhancing friction between the belt and the coil.

Baumgartner discloses an expandable structure (figure 7) for distracting and supporting two substantially opposing tissue surfaces in a patient's body, the device comprising: an expandable structure 2 (figure 6) insertable between the two opposing support surfaces of a wrapping element, adapted to be expanded between the two opposing tissue surfaces to a predetermined dimension (figure 6). The expandable structure 2 comprises a coiled strap (figure 6) that is coiled over a rotor 10 (figure 6; col. 3, lines 56-67). The device further includes a propulsion belt 19 (figures 5 and 6; col. 4, lines 1-10) for driving the strap 2 and enhancing its coiling (col. 4, lines 1-10). The device is provided with a roller 15 for rolling the propulsion belt 19 (figure 6; col. 3, line 65 - col. 4, line 5). The belt 19 is provided with a ragged surface (glass fiber) for enhancing friction (col. 4, lines 1-5). The strap 2 is provided with a ragged surface in the region of numeral 7 (col. 3, lines 48-55, the ragged surface comprising a meshwork of PET threads).

It would have been obvious to one skilled in the art at the time the invention was made to substitute the expandable structure disclosed by Weikel et al. with the expandable structure taught by Baumgartner, to achieve the predictable result of providing an expansion means and providing support to the tissue. Furthermore, the use of the expandable structure of Baumgartner would reduce the possibility of leakage of the expansion medium.

***Response to Arguments***

16. Applicant's arguments with respect to claims 1-31 have been considered but are moot in view of the new ground(s) of rejection.

17. Applicant's arguments with respect to the prior art have been considered but are not persuasive.

Regarding applicant's arguments that the claimed device comprises an integral conduit that remains implanted within the patient's tissues, as opposed to the prior art devices, which applicant contends have separate conduits that do not remain implanted in the body, examiner would like to note that the claim only requires that the device be ***adapted*** to remain implanted in the patient's body (a statement of intended use). With regard the statements of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over the prior art which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Furthermore, the prior art devices ***are adapted*** to remain implanted in the body at least while they are being used, i.e. even though they disclose that the conduits are removed after expansion, for

Art Unit: 3733

some period of time during the implantation of the device, the devices remain implanted.

The claim does not require the devices to remain implanted in their entirety indefinitely.

### ***Conclusion***

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNNSY SCHNEIDER whose telephone number is (571)270-7856. The examiner can normally be reached on Monday - Friday, 9:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571)272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. S./

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733